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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1629	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,145	PREHM, PETER	
	Examiner	Art Unit	
	Gregg Polansky	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-12,37-46 and 70-73* is/are pending in the application.

5a) Of the above claim(s) *45 and 46* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-12,37-44 and 70-73* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/01/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' Information Disclosure Statement, filed 4/01/2011, is acknowledged and has been reviewed. Foreign language documents submitted with English translations have been reviewed only to the extent of the translated portions of the documents.

2. Applicants' provisional election, **without traverse**, in the reply filed on 5/05/2011 of Group I, drawn to a method of treatment, is acknowledged. The Restriction Requirement is thus deemed to be proper and is made **Final**.

3. Applicants' provisional election, **without traverse**, in the reply filed on 5/05/2011 of the species (a) the MRP ABC-transporter subfamily, (b) probenecid as the inhibitor of the MRP subfamily, and (c) osteoarthritis as the disease subject to treatment. The Election of Species requirement is thus deemed to be proper and is made **Final**.

4. The claims are being examined as limited by the elected species, *i.e.*, treating osteoarthritis comprising administering a pharmaceutical composition comprising probenecid.

5. Applicants have amended the claims by cancelling Claims 13-36 and 47-69, and adding Claims 70-73

6. Claims 1-12, 37-46 and 70-73 are pending.

7. Claims 45 and 46 are withdrawn from consideration in accordance with 37 CFR 1.142(b), because they are drawn to non-elected species.

8. Claims 1-12, 37-44 and 70-73 are presently under consideration.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10, 37-41, 42-44, 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 39 contain parenthetical subject matter that renders the claims indefinite because it is not clear whether "juvenile" in parentheses is a limitation or an option for chronic arthritis.

Claims 42-44 contain parenthetical subject matter that renders the claims indefinite because it is not clear whether "ABCC5" in parentheses is a limitation or an option for MRP5.

Regarding claim 37, the abbreviation "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-12, 37-44 and 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan et al. (WO 90/15600).

Nolan et al. teach the treatment of joint disease associated with chronic arthritis (rheumatoid arthritis and **osteoarthritis**). The reference teaches the major consequence of these diseases is loss of function of the affected joints "due to destruction of the major structural components of the joint, cartilage and bone". See page 1, 1st two paragraphs, and page 2, 2nd and 3rd paragraphs.

Nolan et al. specifically claim a method of treating joint degeneration associated with chronic arthritis by administering probenecid. See pages 19 and 20, claims 1 and 7.

The reference teaches treating joint degeneration includes alleviating (i.e., therapeutic treatment) and preventing (i.e., prophylactic treatment) the joint degeneration. See page 2, 2nd full paragraph.

The Nolan et al. disclosure is directed to the treatment of animals, in particular, humans. See page 17, 1st three paragraphs.

Nolan et al. do not teach:

(a) arthritis is associated with an excess transport of hyaluronan across a lipid bilayer;

(b) probenecid inhibits at least one ABC transporter (including the instantly claimed ABC-C (MPR)-subfamily) capable of transporting hyaluronan across a lipid bilayer; or

(c) the ABC-transporter is comprised in a chondrocyte cell.

However, these are all inherent characteristics of the patient and administration of probenecid to the patient. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound

because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

13. Claims 1-10, 12, 37-44 and 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, E. (U.S. Patent No. 4,254,122).

Brown teaches compositions administered to warm blooded animals, including humans, to treat, *inter alia*, **osteoarthritis** and rheumatoid arthritis. Brown teaches the compositions can contain one or more other agents which can have a beneficial effect on the disease. Such additional agents include probenecid. See the paragraph bridging columns 7 to 8.

The open language of the instant claims allows for the inclusion of other agents in addition to the instantly claimed agents (e.g., probenecid).

Brown does not teach:

(a) arthritis is associated with an excess transport of hyaluronan across a lipid bilayer;

(b) probenecid inhibits at least one ABC transporter (including the instantly claimed ABC-C (MPR)-subfamily) capable of transporting hyaluronan across a lipid bilayer; or

(c) the ABC-transporter is comprised in a chondrocyte cell.

However, these are all inherent characteristics of the patient and administration of probenecid to the patient. See *In re Best* and *In re Fitzgerald*, *supra*.

14. Claims 1-12, 37-44 and 70-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Fey et al. (WO 2005/000331 A2; 6/04/2003 priority date).

Fey et al. teach and claim a method of treating, reducing, or preventing a degenerative joint disorder, including osteoarthritis, by administering to a mammal, including humans, a joint enhancing composition that includes probenecid as a second therapeutic agent. See claims 34, 35, 38, 43 and 52.

The open language of the instant claims allows for the inclusion of other agents in addition to the instantly claimed agents (e.g., probenecid).

Fey et al. do not teach:

(a) arthritis is associated with an excess transport of hyaluronan across a lipid bilayer;

(b) probenecid inhibits at least one ABC transporter (including the instantly claimed ABC-C (MPR)-subfamily) capable of transporting hyaluronan across a lipid bilayer; or

(c) the ABC-transporter is comprised in a chondrocyte cell.

However, these are all inherent characteristics of the patient and administration of probenecid to the patient. See *In re Best* and *In re Fitzgerald*, *supra*.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-12, 37-44 and 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (Scandinavian Journal of Rheumatology, 2000, Vol. 29(6), pages 380-386; Abstract only), in view of PDR (Physicians' Desk Reference, 48TH Edition, 1994, "BENEMID® Tablets (Probenecid), U.S.P.", pages 1408-1410).

Sun et al. teach "elevated serum uric acid in the multifactorial etiology of generalized [osteoarthritis]" in humans. See Abstract.

PDR teaches the use of probenecid for the treatment of hyperuricemia associated with gout and gouty arthritis. See page 1408, "INDICATIONS".

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer probenecid to patients suffering from osteoarthritis and elevated serum uric acid. Motivation would have come by recognizing the association of elevated serum uric acid in patients with osteoarthritis and the potential therapeutic and/or prophylactic effect of reducing the elevated serum uric acid.

The cited references do not teach:

(a) arthritis is associated with an excess transport of hyaluronan across a lipid bilayer;

(b) probenecid inhibits at least one ABC transporter (including the instantly claimed ABC-C (MPR)-subfamily) capable of transporting hyaluronan across a lipid bilayer; or

(c) the ABC-transporter is comprised in a chondrocyte cell.

However, these are all inherent characteristics of the patient and administration of probenecid to the patient. See *In re Best* and *In re Fitzgerald*, *supra*.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. Claims 1-12, 37-44 and 70-73 are rejected.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on (571) 272-5541. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1629

/James D Anderson/
Primary Examiner, Art Unit 1629